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EXAMINER

MORAN, MARJORIE A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/637,086

Applicant(s)

FINCHER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 10-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Claims 1 and 10-11 are pending.

***Claim Rejections - 35 USC § 101***

Claims 1, 10 and 11 are again rejected, as previously set forth in the office action of 10/21/02, under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive. Applicant repeats arguments previously set forth in the response of 7/23/02. Specifically, applicant cites several decisions to support that if one utility is known/asserted for a claimed invention, then the invention has utility. The examiner does not argue with this. However, the examiner maintains that applicant has not established a specific, substantial and credible utility for the reasons previously set forth. Applicant again cites 20 USPQ2d 1094, 1100 (Fed. Cir. 1991) as support for the argument that the examiner's position that "the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" is wrong as a matter of law. In response, it is noted the specification teaches only general uses (purposes), but does not teach any specific "purpose" for the elected sequence. The uses argued above are ones which are applicable to the general class of nucleic acids and are not specific to the SEQ ID NO: elected. As previously set forth, it is well known in the art that polynucleotides, including others than those recited in the instant claims, can be used in hybridization assays to detect other nucleic acid sequences. A nucleic acid molecule may have utility based on its use as a marker or probe for or related to a specific disease

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condition or gene known to be correlated with a disease condition (e.g. probes for Huntington's chorea, cystic fibrosis, etc.); however, no correlation between the elected SEQ ID NO: and a specific disease condition is taught by the instant specification. With regard to genetic mapping and determining an Expression Profile, applicant is reminded that, as quoted on page 2 of the "Remarks", that the public must benefit from a "substantial utility....where specific benefit exists in *currently available* form." Emphasis added by the examiner. The is interpreted to mean that a "use" to do further research (i.e. to establish a correlation between a disease and a gene, or to determine expression patterns in particular tissues) is not a specific, substantial and credible utility under 35 USC 101. For these reasons, the general utilities taught by the specification and argued by applicant do not constitute a specific, substantial, and credible utility for the claimed SEQ ID NO's.

Applicants also argue that practical utility of an invention may be derived from belonging to a broad class of inventions. The requirement in any particular case, however, is that practical utility can be inferred if each and every member of the broad class possesses a common utility. However, the fact situation in the instant application is not analogous to applicants' microscope or golf club examples.

For the reasons set forth above and previously set forth, the examiner maintains that the claims lack utility, therefore the rejection of claim 1 is maintained and claims 10-11 are rejected.

Claims 1 and 10-11 are also again rejected under 35 U.S.C. 112, first paragraph for not being enabled.

Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive. Applicant argues that as the claimed nucleic acid sequences have utility, they are

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enabled. This enablement rejection is linked to the utility rejection, as previously set forth. As the utility rejection is maintained, the enablement rejection is also maintained.

***Claim Rejections - 35 USC § 112, 1st paragraph***

Claims 1 and 10 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 1/21/03 have been fully considered but they are not persuasive. Applicants present various arguments and recites several court cases to support that a claim may be broader than specifically taught embodiments and that the specification need not recite every sequence represented by the claim. In addition, applicants argue that the specification provides a detailed chemical structure; i.e. SEQ ID NO: 1 and therefore any modification thereof may be readily envisioned by one of the skill in the art. In response, it is noted that although claims may be broader than embodiments specifically taught by the specification, the specification must nonetheless fully and completely describe the invention such that it is clear that applicants were in possession of the claimed inventions at the time of filing. It is clear, and the previous office action stated, that sequences consisting of SEQ ID NO: 1 are fully described by the instant specification. However, as previously set forth, sequences which comprise SEQ ID NO: 1 encompass a large variety of structures which are not fully and completely described by the instant specification. The specification teaches on page 20 that an embodiment of the claimed invention includes homologs from other plant, fungi, mammals, bacteria, and algae, and teaches that such homologs may have as little as 25% identity with a

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disclosed SEQ ID NO. A sequence which is 75% DIFFERENT from SEQ ID NO: 1 is a very different structure from that of SEQ ID NO: 1. Applicant argues that the examiner has not provided any reasons why one skilled in the art would not recognize a structure which is 75% different from SEQ ID NO: 1 as being in applicant's possession at the time of invention. In response, it is noted that the claimed nucleic acids may be genomic and may therefore comprise introns, noncoding regions, repetitive sequences, etc. These sequence may "comprise" SEQ ID NO: 1 and a vast variety of other nucleic acid sequences. Applicant has not described sufficient members of the genus represented by the claim such that one skilled in the art would recognize that applicants were in possession of the genus. For these reasons and those previously set forth, the examiner maintains that the variety of structures embodied in the claims is not fully described by the instant specification and that one skilled in the art would not be able to readily envision the members of the genus represented by the claims, therefore the rejection of claims 1 and 10 is maintained..

Claim 1 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

A nucleic acid molecule or fragment thereof which encodes a cotton protein or fragment thereof is not described by the originally filed specification. The instant specification discloses on page 1 that the instantly claimed nucleic acids encode cotton proteins, but is silent with respect to any specific proteins encoded. The specification does not disclose that SEQ ID NO: 1 actually encodes any protein or peptide, nor does the specification disclose an open reading (ORF) or other evidence that SEQ ID NO: 1 does, in fact, encode a polypeptide of any kind.

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SEQ ID NO: 1 comprises at least two putative start codons (ATG's), therefore it is possible, as argued by applicants, that SEQ ID NO: 1 MAY encode at least a fragment of a protein.

However, it is unknown which of the possible start codons represents the start of an ORF, or if the sequence actually encompasses a functional ORF (i.e. one which includes both a start and stop codon in the same reading frame). In addition, while the nucleic acid sequence was isolated from cotton, the specification does not disclose whether a protein or peptide encoded by SEQ ID NO: 1 is specific to cotton, or may be one which is found in a variety of organisms. Applicant argues that the nucleic acids were isolated from cotton plants, thereby implying that a protein encoded must be a cotton plant. In response, and by way of example, if the claimed nucleic acid were capable of expressing a protein, and were transfected into another cell or plant type, would the protein expressed still be identifiable as originating in cotton? The specification is silent with respect to markers or any other way of differentiating an encoded protein as being specific to cotton. As the specification does not disclose any protein or peptide encoded by SEQ ID NO: 1, particularly one which is known to be specific to cotton, the rejection is maintained.

### ***Conclusion***

Claims 1 and 10-11 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*

mam  
April 7, 2003